

REMARKS

Applicant respectfully requests reconsideration. Claims 1-5, 25 and 28-38 are pending in this application. Claim 25 is hereby amended without prejudice or disclaimer. No new claims have been added. As a result, claims 1-5, 25 and 28-38 remain pending. Of these, claims 1-5, 37 and 38 are withdrawn from consideration. No new matter has been added.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 25 and 28-35 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,384,239 (Saunders; Publication date of January 24, 1999).

In response, Applicant has amended claim 25 without prejudice or disclaimer to clarify that the blood glucose level history of a subject is obtained for predetermined time intervals by sorting red blood cells as a function of a detected amount of glycated hemoglobin to generate a cell distribution profile that is divided into a series of consecutive bins each containing a number of cells representing a predetermined time interval. Differences between glycated hemoglobin levels at the edges of each of the bins are calculated, and the calculated differences in levels of glycated hemoglobin are converted into blood glucose levels for the predetermined time intervals.

Accordingly, both the time intervals and the blood glucose levels are determined based on the detected amount of glycated hemoglobin. In contrast, Applicant submits that Saunders teaches generating time-resolved glycohemoglobin curves by methods that are not based on the amount of glycated hemoglobin. For example, column 3, lines 7-10, of Saunders teaches that “[i]n a preferred embodiment, red blood cells from a single sample are separated according to age into a plurality of age cohorts, e.g., by capillary centrifugation.” Column 4, lines 13-14, teaches that “[r]ed blood cells (RBCs) may be fractionated according to age by density gradient methods.” Column 4, lines 19-21 teaches that “[p]hysical separation of the red blood cells is not required if cells of different ages can otherwise be distinguished.” However, Saunders fails to teach or suggest using detected amounts of glycated hemoglobin in intact red blood cells to sort cells by age.

On page 3 of the Office Action, the Examiner cited several passages of Saunders as teaching “generating a cell distribution profile” and “dividing cell distribution into bins.” The

Examiner also stated on page 5 of the Office Action that “Saunders teaches that blood glucose levels are related to the slope of the time-resolved glycohemoglobin curves.” However, Applicant respectfully submits that none of these passages teach or suggest using glycated hemoglobin levels to generate a cell distribution profile that is divided into a series of consecutive bins each containing a number of cells representing a predetermined time interval. To the contrary, Applicant submits that Saunders teaches generating time-resolved glycohemoglobin curves by methods that are not based on the amount of glycated hemoglobin as explained above.

Accordingly, Saunders fails to even suggest, let alone teach, methods that use a detected amount of glycated hemoglobin in intact red blood cells to determine both a time interval and a glucose level in a patient during that time interval.

Accordingly, reconsideration and withdrawal of the rejection of claim 25, and dependent claims 28-35, under 35 U.S.C. §102 is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 25 and 36 under 35 U.S.C. §103(a) as being unpatentable over 5,384, 239 (Saunders; Publication date of January 24, 1999), as applied to claim 25 above, in view of Burshteyn et al. (filing date of 25 April 2003).

Applicant respectfully submits that Burshteyn et al. also fails to suggest or teach methods that use a detected amount of glycated hemoglobin in intact red blood cells to determine both a time interval and a glucose level in a patient during that time interval as explained in detail above. Therefore, Saunders in view of Burshteyn et al. cannot form the basis for a continued rejection of either claim 25 or dependent claim 36 under 35 U.S.C. §103(a).

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. E0444.70000US01.

Respectfully submitted,

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